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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED, and
ASTRAZENECA AB,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

Case No. 1:18-cv-11238-RMB-KMW

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB (collectively "Plaintiffs" or "AstraZeneca") bring this action for patent infringement against Apotex Inc. and Apotex Corp. ("Defendants" or "Apotex").

THE PARTIES

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850, U.S.A.

2. Plaintiff AstraZeneca UK Limited is a private limited company organized under

the laws of England and Wales, with its registered office at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, United Kingdom, CB2 0AA.

3. Plaintiff AstraZeneca AB is a public limited liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

4. On information and belief, Defendant Apotex Inc. is a Canadian corporation, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

5. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. On information and belief, Defendants are in the business of manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this District.

7. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

8. On information and belief, Defendants acted in concert to develop the Proposed ANDA Product that is the subject of Abbreviated New Drug Application (“ANDA”) No. 211730, and to seek regulatory approval from the U.S. Food and Drug Administration (“FDA”) to market and sell a proposed Fulvestrant Injectable, 50 mg/ml product throughout the United States, including within this District.

9. On information and belief, Apotex Corp. acts as the U.S. agent of Apotex Inc. with respect to ANDA No. 211730, and Apotex Corp. will work, either directly or indirectly, to manufacture, import, market, and sell the Proposed ANDA Product.

NATURE OF THE ACTION

10. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendants' filing of ANDA No. 211730 with the FDA.

11. Defendants are seeking approval to engage in the commercial manufacture, use and sale of a proposed Fulvestrant Injectable, 50 mg/ml product (the "Proposed ANDA Product") prior to the expiration of AstraZeneca's U.S. Patent Nos. 6,774,122, 7,456,160, 8,329,680, and 8,466,139.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over Defendants because Defendants have maintained continuous and systematic contacts with the State of New Jersey and this District.

14. On information and belief, Defendants market and sell brand and generic pharmaceutical products throughout the United States, including in the State of New Jersey, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, brand and generic pharmaceutical products. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

15. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial, continuous, and systematic contacts with the State of New Jersey. On information and belief, Apotex Inc.: (1) intentionally markets and provides its generic

pharmaceutical products to residents of this State; (2) enjoys substantial income from this State; (3) created a presence in this State through its subsidiary agent, Apotex Corp., a company registered with the State of New Jersey as a drug wholesaler under Registration No. 5003192; and (4) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction.

16. The Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial, continuous, and systematic contacts with the State of New Jersey. On information and belief, Apotex Corp.: (1) intentionally markets and provides its generic pharmaceutical products to residents of this State; (2) enjoys substantial income from this State; (3) created a presence in this State through its registration with the New Jersey Department of Health and Senior Services Consumer and Environmental Health service as a drug wholesaler and maintains a Drug and Medical Device Certificate of Registration under Registration No. 5003192; and (4) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction. Moreover, Apotex Corp., by virtue of its registration with the New Jersey Department of Health and Senior Services Consumer and Environmental Health service a drug wholesaler, is required to either designate an agent for service of process or, by default, consent to the New Jersey Secretary of State as its agent pursuant to NJAC § 8:21-3A and NJSA § 24:6B-15.

17. On information and belief, Apotex Inc. directly or through its subsidiaries, including Apotex Corp., manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district.

18. On information and belief, Defendants intend to manufacture for distribution, and to distribute and sell their Proposed ANDA Product throughout the United States and in this judicial district. Defendants' filing of ANDA No. 211730 confirms this intention and additionally subjects Defendants to the specific personal jurisdiction of this Court. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

19. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

THE PATENTS-IN-SUIT

20. United States Patent No. 6,774,122 (the "'122 Patent"), entitled "Formulation," was duly and legally issued on August 10, 2004 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '122 Patent. AstraZeneca UK Limited is the beneficial owner of the '122 Patent. A copy of the '122 Patent is attached as **Appendix A**.

21. United States Patent No. 7,456,160 (the "'160 Patent"), entitled "Formulation," was duly and legally issued on November 25, 2008 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '160 Patent. AstraZeneca UK Limited is the beneficial owner of the '160 Patent. A copy of the '160 Patent is attached as **Appendix B**.

22. United States Patent No. 8,329,680 (the "'680 Patent"), entitled "Formulation," was duly and legally issued on December 11, 2012 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '680 Patent. AstraZeneca UK Limited is the beneficial owner of the '680 Patent. A copy of the '680 Patent is attached as **Appendix C**.

23. United States Patent No. 8,466,139 (the "'139 Patent"), entitled "Formulation,"

was duly and legally issued on June 18, 2013 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '139 Patent. AstraZeneca UK Limited is the beneficial owner of the '139 Patent. A copy of the '139 Patent is attached as **Appendix D**.

FACTUAL BACKGROUND

FASLODEX[®] (fulvestrant) intramuscular injection

24. FASLODEX[®] (fulvestrant) intramuscular injection is an estrogen receptor antagonist approved by the FDA for the treatment of: (a) hormone receptor positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy; and (b) hormone receptor positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression following endocrine therapy.

25. FDA regulatory exclusivity for the treatment of hormone receptor positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression following endocrine therapy will expire on February 19, 2019.

26. AstraZeneca UK Limited is the holder of approved New Drug Application ("NDA") No. 21-344 for FASLODEX[®] (fulvestrant) intramuscular injection, in 50 mg/mL dosage forms. AstraZeneca Pharmaceuticals LP is the authorized agent for matters related to NDA No. 21-344 in the United States.

27. The use of FASLODEX[®] (fulvestrant) intramuscular injection is covered by one or more Claims of the '122, '160, '680, and '139 Patents.

28. The '122, '160, '680, and '139 Patents have been listed for NDA No. 21-344 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

29. AstraZeneca Pharmaceuticals LP sells and distributes FASLODEX[®] (fulvestrant) intramuscular injection in the United States pursuant to NDA No. 21-344.

DEFENDANTS' ANDA

30. By Notice Letter dated May 30, 2018, Defendants notified AstraZeneca that Defendants' ANDA No. 211730 ("Defendants' ANDA") was submitted to the FDA and that Defendants are seeking approval to engage in the commercial manufacture, use and sale of the Proposed ANDA Product prior to the expiration of the '122, '160, '680, and '139 Patents, and included within ANDA No. 211730 a certification pursuant to 21 U.S.C. § 355(j)(2)(b)(iv)(II) ("Paragraph IV Certification") that the '122, '160, '680, and '139 Patents are invalid and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product.

31. Defendants were aware of the Patents-in-Suit when ANDA No. 211730 was filed with a Paragraph IV Certification.

32. On information and belief, Defendants' ANDA No. 211730 refers to and relies upon AstraZeneca's FASLODEX[®] (fulvestrant) intramuscular injection NDA and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and FASLODEX[®] (fulvestrant) intramuscular injection.

33. On information and belief, the Proposed ANDA Product label will have instructions for use that substantially copy the instructions for FASLODEX[®] (fulvestrant) intramuscular injection, including instructions for administering the Proposed ANDA Product by intramuscular injection to treat hormone dependent breast cancer. The instructions accompanying the Proposed ANDA Product will induce others to use and/or contribute to others' use of the Proposed ANDA Product in the manner set forth in the instructions.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,774,122

34. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–33 of this Complaint.

35. The use of the Proposed ANDA Product is covered by one or more Claims of the '122 Patent.

36. Defendants' submission of ANDA No. No. 211730 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '122 Patent constitutes infringement of one or more Claims of the '122 Patent under 35 U.S.C. § 271(e)(2).

37. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. No. 211730 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

38. The Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '122 Patent under 35 U.S.C. § 271(a).

39. Upon FDA approval of ANDA No. No. 211730, Defendants will infringe the '122 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

40. On information and belief, Defendants had knowledge of the '122 Patent when they submitted ANDA No. No. 211730 to the FDA and Defendants know or should have known that they will aid and abet another's direct infringement of at least one of the Claims of the '122

Patent.

41. The Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the '122 Patent.

42. Defendants had knowledge of the '122 Patent and are knowingly and willfully infringing the '122 Patent.

43. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

44. On information and belief, Defendants lacked a good faith basis for alleging invalidity and/or non-infringement of the '122 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants' Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF
U.S. PATENT NO. 6,774,122

45. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–44 of this Complaint.

46. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

47. On information and belief, Defendants have taken and plan to, intend to, and will take active steps to induce, or contribute to, the infringement of the '122 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 211730 is approved.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,456,160

48. Plaintiffs hereby reallege and incorporate by reference the allegations of

paragraphs 1–47 of this Complaint.

49. The use of the Proposed ANDA Product is covered by one or more Claims of the '160 Patent.

50. Defendants' submission of ANDA No. 211730 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '160 Patent constitutes infringement of one or more Claims of the '160 Patent under 35 U.S.C. § 271(e)(2).

51. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 211730 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

52. The Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '160 Patent under 35 U.S.C. § 271(a).

53. Upon FDA approval of ANDA No. 211730, Defendants will infringe the '160 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

54. On information and belief, Defendants had knowledge of the '160 Patent when they submitted ANDA No. 211730 to the FDA and Defendants know or should have known that they will aid and abet another's direct infringement of at least one of the Claims of the '160 Patent.

55. The Notice Letter lacks any legitimate legal or factual basis for non-infringement

of any Claims of the '160 Patent.

56. Defendants had knowledge of the '160 Patent and are knowingly and willfully infringing the '160 Patent.

57. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

58. On information and belief, Defendants lacked a good faith basis for alleging invalidity and/or non-infringement of the '160 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants' Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

**COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF
U.S. PATENT NO. 7,456,160**

59. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–58 of this Complaint.

60. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

61. On information and belief, Defendants have taken and plan to, intend to, and will take active steps to induce, or contribute to, the infringement of the '160 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 211730 is approved.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 8,329,680

62. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–61 of this Complaint.

63. The use of the Proposed ANDA Product is covered by one or more Claims of the

'680 Patent.

64. Defendants' submission of ANDA No. 211730 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '680 Patent constitutes infringement of one or more Claims of the '680 Patent under 35 U.S.C. § 271(e)(2).

65. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 211730 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

66. The Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '680 Patent under 35 U.S.C. § 271(a).

67. Upon FDA approval of ANDA No. 211730, Defendants will infringe the '680 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

68. On information and belief, Defendants had knowledge of the '680 Patent when they submitted ANDA No. 211730 to the FDA and Defendants know or should have known that they will aid and abet another's direct infringement of at least one of the Claims of the '680 Patent.

69. The Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the '680 Patent.

70. Defendants have knowledge of the '680 Patent and are knowingly and willfully

infringing the '680 Patent.

71. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

72. On information and belief, Defendants lacked a good faith basis for alleging invalidity and/or non-infringement of the '680 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants' Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

**COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF
U.S. PATENT NO. 8,329,680**

73. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–72 of this Complaint.

74. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

75. On information and belief, Defendants have taken and plan to, intend to, and will take active steps to induce, or contribute to, the infringement of the '680 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 211730 is approved.

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 8,466,139

76. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–75 of this Complaint.

77. The use of the Proposed ANDA Product is covered by one or more Claims of the '139 Patent.

78. Defendants' submission of ANDA No. 211730 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale

and/or offer for sale of the Proposed ANDA Product before the expiration of the '139 Patent constitutes infringement of one or more Claims of the '139 Patent under 35 U.S.C. § 271(e)(2).

79. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 211730 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

80. The Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '139 Patent under 35 U.S.C. § 271(a).

81. Upon FDA approval of ANDA No. 211730, Defendants will infringe the '139 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

82. On information and belief, Defendants had knowledge of the '139 Patent when they submitted ANDA No. 211730 to the FDA and Defendants know or should have known that they will aid and abet another's direct infringement of at least one of the Claims of the '139 Patent.

83. The Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the '139 Patent.

84. Defendants have knowledge of the '139 Patent and are knowingly and willfully infringing the '139 Patent.

85. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate

remedy at law.

86. On information and belief, Defendants lacked a good faith basis for alleging invalidity and/or non-infringement of the '139 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants' Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

**COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF
U.S. PATENT NO. 8,466,139**

87. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–86 of this Complaint.

88. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

89. On information and belief, Defendants have taken and plan to, intend to, and will take active steps to induce, or contribute to, the infringement of the '139 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 211730 is approved.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

- a) Judgment that the '122, '160, '680, and '139 Patents are valid and enforceable;
- b) Judgment that Defendants' submission of ANDA No. 211730 was an act of infringement of one or more Claims of the '122, '160, '680, and '139 Patents under 35 U.S.C. § 271(e)(2);
- c) Judgment that Defendants' making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Product prior to the

expiration of the '122, '160, '680, and '139 Patents, will directly infringe, will actively induce infringement, and/or will contribute to the infringement of one or more Claims of the '122, '160, '680, and/or '139 Patents;

d) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 211730 shall be a date that is not earlier than the expiration of the '122, '160, '680, and '139 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

e) An Order permanently enjoining Defendants, their affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Defendants, from making, using, offering to sell, selling, marketing, distributing, or importing into the United States the Proposed ANDA Product until after the expiration of the '122, '160, '680, and '139 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

f) Judgment declaring that infringement, inducement or contributory infringement of the '122, '160, '680, and/or '139 Patents by Defendants is willful should Defendants commercially manufacture, use, offer to sell, sell, or import into the United States the Proposed ANDA Product;

g) A declaration that this case is an exceptional case within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

h) Plaintiffs' reasonable costs and expenses in this action; and

i) Such further and other relief as this Court deems proper and just.

Dated: August 3, 2018

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter of the following actions:

- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. SANDOZ INC., and SANDOZ INTERNATIONAL GmbH*, C.A. No. 1:14-cv-03547-RMB-KMW (“*AstraZeneca v. Sandoz*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. SAGENT PHARMACEUTICALS, INC.*, C.A. No. 1:14-cv-05539-RMB-KMW (“*AstraZeneca v. Sagent*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. GLENMARK PHARMACEUTICALS INC., USA*, C.A. No. 1:15-cv-00615-RMB-KMW (“*AstraZeneca v. Glenmark*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. AGILA SPECIALTIES, INC. F/K/A STRIDES INC., ONCO THERAPIES LIMITED, MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC.*, C.A. No. 1:15-cv-06039-RMB-KMW (“*AstraZeneca v. Agila*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC.*, C.A. No. 1:15-cv-07009-RMB-KMW (“*AstraZeneca v. Mylan*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. TEVA PHARMACEUTICALS USA, INC.*, C.A. No. 1:15-cv-07889-RMB-KMW (“*AstraZeneca v. Teva Second Wave*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. INNOPHARMA, INC.*, C.A. No. 1:16-cv-00894-RMB-KMW (“*AstraZeneca v. InnoPharma Inc.*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. INNOPHARMA LICENSING LLC*, C.A. No. 1:16-cv-01962-RMB-KMW (“*AstraZeneca v. InnoPharma Licensing*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. MYLAN INSTITUTIONAL LLC*, C.A. No. 1:16-cv-04612-RMB-KMW (“*AstraZeneca v. Mylan Institutional*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. DR. REDDY’S LABORATORIES, INC. and DR. REDDY’S LABORATORIES, LTD.*, C.A. No. 1:17-cv-00926-RMB-KMW (“*AstraZeneca v. Dr. Reddy’s*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. AMNEAL PHARMACEUTICALS LLC*, C.A. No. 1:17-cv-01968-RMB-KMW (“*AstraZeneca v. Amneal*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. HBT LABS, INC.*, C.A. No. 1:17-cv-02652-RMB-KMW (“*AstraZeneca v. HBT*”)

- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. TEVA PHARMACEUTICALS USA, INC.*, C.A. No. 1:17-cv-02448-RMB-KMW (“*AstraZeneca v. Teva*”)
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. FRESENIUS KABI USA, LLC*, C.A. No. 1:17-cv-13075-RMB-KMW (“*AstraZeneca v. Fresenius*”)

The foregoing cases involve AstraZeneca’s FASLODEX[®] (fulvestrant) intramuscular injection product. The FASLODEX[®] (fulvestrant) intramuscular injection cases have been assigned to Hon. Renée M. Bumb, U.S.D.J. The *AstraZeneca v. Sandoz*, *AstraZeneca v. Sagent*, and *AstraZeneca v. Glenmark* cases were consolidated by Judge Bumb under lead case, *AstraZeneca Pharms. LP, et al. v. Sandoz Inc., et al.*, Civ. No. 14-cv-03547. The *AstraZeneca v. Agila*, *AstraZeneca v. Mylan*, *AstraZeneca v. Teva Second Wave*, *AstraZeneca v. Mylan Institutional*, and *AstraZeneca v. InnoPharma Licensing* cases were consolidated by Judge Bumb under Consolidated Case No. 1:15-cv-06039. To date, the following cases have been terminated: *AstraZeneca v. Sandoz*, *AstraZeneca v. Sagent*, *AstraZeneca v. Glenmark*, *AstraZeneca v. InnoPharma Inc.*, *AstraZeneca v. Agila*, *AstraZeneca v. Mylan*, *AstraZeneca v. Mylan Institutional*, *AstraZeneca v. Dr. Reddy’s*, *AstraZeneca v. Teva Second Wave*, *AstraZeneca v. InnoPharma Licensing*, *AstraZeneca v. HBT*, *AstraZeneca v. Amneal*, *AstraZeneca v. Teva*, and *AstraZeneca v. Fresenius*. Plaintiffs respectfully request that this case likewise be assigned to Judge Bumb due to her familiarity with the subject matter.

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Respectfully submitted,

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